SEP 12 2007

Section I 510(k) Summary of Safety and Effectiveness

K072021

Applicant:

NeoForce Group Inc
35 Commerce Drive
Ivyland, Pa 18974
Registration Number: 3005599562

Contact Person:

Monica Ferrante
VP Regulatory
Ph 215-672-6800
Fax 215-672-1123

Device trade/proprietary name:

NeoPIP Infant Resuscitation Unit

Device common/usual/classification name:

Emergency Resuscitation Device

Classification:

Anesthesiology
21 CFR 868.5915
Manual Emergency Ventilator, BTM, Class II

Performance Standards:

None applicable

Predicate Device:

K892885 Fisher & Paykel, Neopuff Infant Resuscitator

Device Description

The NeoPIP Infant Resuscitation Unit is intended to deliver oxygen or blended gas to a neonate while controlling peak inspiratory pressure. Positive end expiratory pressure is controlled at the patient end of the breathing circuit. The device also provides a maximum pressure relief capability which is adjustable. The device is intended for emergency resuscitation and is manually operated.

Intended Use

The NeoPIP Infant Resuscitation Unit is a manually operated, gas powered device intended for controlled and accurate resuscitation of neonates and infants in the clinical environment.

Substantial Equivalence

The NeoPIP is believed to be substantially equivalent to currently marketed manual emergency resuscitation devices with regards to intended use, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2007

Ms. Monica Ferrante
Vice President Regulatory
NeoForce Group, Incorporated
35 Commerce Drive
Ivyland, Pennsylvania 18974-1510

Re: K072021
Trade/Device Name: NeoPIP Infant Resuscitation Unit
Regulation Number: 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: July 20, 2007
Received: July 23, 207

Dear Ms. Ferrante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K072021

Device Name: NeoPIP Infant Resuscitation Unit

Indications for Use:

The NeoPIP Infant Resuscitation Unit is a manually operated, gas powered device intended for controlled and accurate resuscitation of neonates and infants in the clinical environment.

Prescription Use __X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K072021